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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,129	08/05/2002	David Norman Wells	36697.6	1451

27683 7590 07/25/2007

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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/088,129	WELLS, DAVID NORMAN	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/3/07.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17, 19, 24-27, 34-46, 49-59, 62-66 is/are pending in the application.

4a) Of the above claim(s) 34-46, 49-55, 57 and 58 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17, 19, 24-27, 56, 59, 62-66 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/13/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Amendment, filed 1/29/07 is not entered because the amendment is non-compliant.

Applicants' Amendment, filed 5/3/07, is compliant and has been entered. Claims 1-17, 19, 24-27, 34-46, 49-59, 62-66 are pending; claims 18, 60 and 61 are cancelled; claims 34-46, 49-55, 57 and 58 are withdrawn; claims 1, 2, 9, 10, 13, 16, 17, 19, 24-27, 56, 59, 62-66 are amended; claims 1-17, 19, 24-27, 56, 59, 62-66 are under current examination.

Applicants filed Remarks on 1/29/07, which the Examiner addresses in this Office Action.

This action is non-final.

Election/Restrictions

Claims 34-46, 49-55, 57 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/6/06.

Information Disclosure Statement

Applicants' IDS, filed 10/13/06, has been considered.

Claim Objections

The prior objections to claims 10, 24 are withdrawn in view of Applicants' amendment to the claims.

The prior objection to claims 31 and 32 is rendered moot in view of Applicants' cancellation of the claims.

Claim Rejections - 35 USC § 101

The prior rejection of claims 20, 22, 23, 28, 29 and under 35 U.S.C. 101 as being directed to non-statutory subject matter, is rendered moot in view of Applicants' cancellation of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17, 19, 24-27, 56, 59, 62-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Applicants have now amended the claims to recite "with the proviso that said method does not result in the production of a primate embryo" (see, for example, claim 1, last 2 lines). Furthermore, Applicants have amended claims 16 and 56 to recite transferring the embryo to a surrogate female of a "closely-related species" in order to produce a cloned, non-primate animal embryo. Applicants have not point to where support for these limitations can be found in the as-filed disclosure.

MPEP §2173.05(i) states that, "Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the]

specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement."

In the instant case, the negative limitation that the method does not result in the production of a primate embryo fails to find support in the as-filed disclosure and constitutes new matter. For example, p. 7, lines 10-12, and p. 8, line 1, include the production of a primate embryo. There appears to be no basis in the original disclosure for this amendment.

Additionally, the limitation of transferring an embryo produced by NT into a surrogate female of a "closely-related" species fails to find support in the as-filed disclosure and constitutes new matter.

To the extent that the claimed methods are not described in the instant disclosure, claims 1-17, 19, 24-27, 56, 59, 62-66 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as

filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17, 19, 24-27, 56, 59, 62-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

1) Methods of nuclear transfer, comprising selecting and segregating non-primate mammalian G1 cells from a proliferating or non-proliferating population of non-primate mammalian donor cells, by identifying mitotic cells growing on glass coverslips using a microscope for the visualization of condensed chromatin on a mitotic spindle, or by identifying condensed chromatin in a cell doublet, still connected by a cytoplasmic bridge, undergoing the telophase stage of mitosis; individually picking mitotic cells in anaphase or telophase off the coverslips, allowing the selected cells to complete mitosis and cleave in two, selecting an individual cell and transferring the intact cell or the nucleus of the segregated cell, within three hours of picking the cell to ensure the cell is in early G1, into an enucleated, non-primate mammalian oocyte;

2) Methods of producing cloned non-primate mammalian embryos by said methods of nuclear transfer;

3) Methods of cloning a non-primate mammal, comprising the steps of producing a non-primate mammalian embryo, as recited above, transferring the embryo to a non-primate, mammalian surrogate mother of the same species, allowing the non-primate embryo to develop to produce a live born non-primate mammal,

The specification does not reasonably provide enablement for the breadth of the claims, which are directed to using enucleated stem cells as recipient cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Applicants' Arguments. Applicants' argue that the as-amended claims are now fully enabled, because the specification teaches methods of NT to produce non-primate embryos using suitable donor and recipient cells. Applicants argue that the claims have now been recited to exclude the possibility of producing a non-primate embryo, and the recipient cell has been amended to recite an oocyte or stem cell. Applicants argue that nuclear transfer merely requires the removal of the nuclear material from one cell (*i.e.*, recipient) and transfer of donor DNA. Applicants argue that there is sufficient evidence in the literature to support the use of oocyte and stem cell cytoplasm for use in NT to generate either cloned animals, or reprogrammed cells, respectively. See page 17 of the Response.

In particular, Applicants argue that if the recipient is an oocyte, then NT can be used to produce a cloned embryo. Applicants argue that if the recipient cell is

from an existing ES cell line, then the nuclear DNA can be reprogrammed such that the resultant cell may be dedifferentiated, and that although this method does involve NT, it does not yield cells that are capable of forming an embryo or offspring. Applicants argue that these hybrid cells may be directed to produce specific cells, for example, for therapeutic purposes. Applicants provide Tada *et al.* as evidence that these hybrid cells contained both sets of nuclear DNA, one from the stem cell and one from the somatic cell, which confirms that cytoplasm can be used successfully in NT. Applicants argue that the claims that are directed to cloning a non-primate mammal, the recipient cell has been restricted to an enucleated oocyte. See page 18 of the Response.

Response To Arguments. Applicants' arguments have been considered, but are not persuasive with regard to the recipient cell that is used in the NT methods. Applicants cite Tada as evidence for reprogramming using a stem cell. Tada used primordial germ cells (PGCs) in order to reprogram thymic lymphocytes. In particular, Tada teach that there were striking changes in the demethylation of several imprinted and non-imprinted genes (see Abstract). Tada teaches one particular cell type (PGCs) that used to reprogram thymic lymphocytes. Shamblott (PNAS, 95: 13726-13731, November 1998) teach that primordial germ cells are considered pluripotent stem cells that closely resemble EG cells (see Abstract, last sentence). The breadth of the instant claims, as stated in the prior Office action, is to any enucleated stem cell; thus, this encompasses any stem cell (which include pluripotent, multipotent and totipotent stem cells), or embryonic stem cells, for use in NT methods. Thus, there is no guidance, with regard to utilizing the breadth of stem cells encompassed by the claims, in successful NT methods. Furthermore, Tada *et al.* are not within the scope of the claimed invention, which requires that the stem cell is enucleated. Tada *et al.* teach the fusion of thymic lymphocytes with EG cells, to produce hybrid, tetraploid cells. This is not analogous to the instantly claimed method, which requires the use of an enucleated stem cell, and thus, Tada

do not provide any prediction with regard to the use of an enucleated stem cell. Applicants' citations of Tada (2003) and Cowan (2005) are not of record, and therefore have not been considered. See also, Campbell and Fulka, cited previously, with respect to the unpredictability in the art in using other recipient cells other than oocytes.

Applicants' Arguments. Applicants argue that they have now amended the claims to recite that the NT embryo is then transferred to a surrogate female of the same or "closely-related" species. Applicants argue that a person of skill in the art would know that the embryo would need to be gestated in a suitable uterine environment, utilizing a recipient female from the same or closely related species, and provide various examples:

> 1.Cloned embryos produced using Ovis orientalis musimon donor nuclei transferred into domesticated sheep, Ovis aries (Loi et al., 2001).
>
> 2. Cloned embryos produced using Bos gaurus donor nuclei transferred into Bos taurus domesticated cattle (Lanza et al., 2000; Vogel, 2001).
>
> 3. Grant's zebra embryos transferred into domestic mares (Summers et al., 1987).

Response To Arguments. Applicants' arguments have been considered, but are not found to be persuasive. In particular, although the art provides specific examples, where animals within the same taxonomical genus have been used in order to produce embryos/live born offspring, Applicants have provided no enabling disclosure with regard to the term "closely-related", and as such, the breadth of this term renders the claim non-enabling, because one of skill in the art would have had to practice undue experimentation to determine how closely related a species must be in order to produce a viable offspring, as required by the claims.

Methods of isolating a G1 cell. Applicants have provided arguments to overcome the §103 rejections of record, because Applicants have argued that their invention is not legally obvious. In particular, Applicants claim that the prior art

(Campbell), although suggesting utilizing a G0 or G1 phase donor cell in NT, they do not use anything other than G0 cells. Furthermore, Applicants argue that the prior art of Collas is limited to utilizing embryonic blastomeres that were in G1, but they did not use somatic cells that were in G1 (see page 23). Additionally, Applicants argue that prior to the time of the claimed invention, many pieces of art (including Wilmut (1997), cited by Applicants) discussed the criticality of utilizing a G0 cell, and that early publications utilizing differentiated cells from unsynchronized cell populations, some of which would be expected to be in G1, for example, Collas & Barnes (1994) who used bovine granulose cells, which possess a naturally long G1 phase, failed to produce any cloned offspring. See page 24-25 of the Response. Thus, Applicants argue, that the art does not provide specific teachings for utilizing a G1 cell as a nuclear donor in NT. Additionally, Applicants argue that it was both "surprising and unexpected" from the studies reported in the present application that differentiated donor cells in G1 could be used successfully in NT. See page 25 of the Response. Applicants argue that the cited art of record (Boquest and Prather) do not provide specific teachings to produce a pure population of cells at G1, or any other cell cycle stage. Applicants argue that the flow cytometry used by Boquest and Prather would render the cells unviable for NT because of ethanol fixation. Applicants further argue that the sorting methodology used does not provide a clear cut-off in protein or DNA content between cell cycle states as measured flow cytometry. Applicants argue that Boquest and Prather describe a visual method discrimination that sets arbitrary gates/boundaries to identify G0 and G1 cells and that no biological corroboration is provided for the G0/G1 cut-off point chosen, and that it was a subjective estimate. Applicants further state that natural variation in DNA and protein content between cells, as well as variation in the accuracy of measurement means there will be significant error in the methods taught and suggested by the art. Applicants argue that neither Prather nor Boquest provide an accurate or reliable method for isolation a

pure population of cells. See pages 26-27 of the Response. Applicants state that this application describes for the first time, a specific method that enables one to repeatedly isolate G1 cells at the time of NT, and that this methodology was developed to ensure that each donor cell was in the definitive G1-phase of the cell cycle. See page 29 of the Response.

In light of Applicants' arguments, the Examiner has determined that, because the state of the art does not provide a reasonable expectation of success, and in fact, as stated by Applicants, shows unpredictability, in reproducibly selecting G1 cells, and utilizing these cells for NT, one of skill in the art would have had to practice undue experimentation, to arrive at the claimed invention. Thus, the enabled scope of the claimed invention has been limited to Applicants' method for identification and isolation of G1 cells. As Applicants have argued, because the state of the art suggested, although did not use G1 cells for NT, and further, the art did not provide a reliable and predictable method for isolating G1 cells.

MPEP §2164.03 states that, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. ... The "predictability or lack thereof' in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of the change within the subject matter to which the claimed invention pertains, there is a lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability."

Thus, given that Applicants state that they have provided a novel method in which to isolate G1 cells, the enabled scope has been limited to this method.

Accordingly, in view of the lack of teachings or guidance provided by the specification with regard to the production of the breadth of the claims, with regard to using enucleated stem cells as the recipient cells, in NT methods, the lack of teachings or guidance with regard to the use of any recipient cell, other than an enucleated oocyte, the breadth of the claims, which are directed to any method of selecting and segregating G1 cells from a population of donor cells, it would have required undue experimentation for one of skill in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 112

The prior rejections of claims 2, 9, 13, 17, 21, 23, 29, and 30 are withdrawn in view of Applicants' amendment or cancellation of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 17, 18, 24-27 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "closely-related" in claim 16 is a relative term which renders the claim indefinite. The term "closely-related" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. One of skill in the art would not be able to determine how closely-related a species would be to be within the metes and bounds of this term, and thus, the term is indefinite. Claims 17, 19, 24-27 depend from claim 16. Similarly, claim 56 recites the term "closely related".

Claim Rejections - 35 USC § 102

The following rejections are rendered moot in view of Applicants' cancellation of the claims:

The prior rejection of claims 20, 22, 23, 28, 29 and 33 under 35 U.S.C. 102(b) as being anticipated by McLaughlin.

The prior rejection of claims 20-23, 28-30, 32 and 33 under 35 U.S.C. 102(b) as being anticipated by Schnieke.

The prior rejection of claims 20-23, 28-33 under 35 U.S.C. 102(b) as being anticipated by Bowen.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, 12, 13 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Collas *et al.* (**Biol. of Reprod.**, 46: 492-500 (1992), Applicants' IDS, filed 10/13/06).

Collas teach the transplantation of synchronized G1 blastomeres into enucleated rabbit oocytes. They teach synchronizing embryos in colcemid to arrest them in metaphase, and then blocked the cells at G1/S using aphidicolin. See Abstract, and p. 494, 2nd col. They teach segregation of the G1 cells by synrhonization by establishing the length of the G1 phase in 16 and 32 cell embryos (see 495, col. 1-2, Length of the G1 Phase in Early Rabbit Embryos).

Accordingly, Collas teach the claimed invention.

Claims 1-3, 6-8, 12, 13 and 62 are rejected under 35 U.S.C. 102(b) as being anticiapted by Otaegui (**Mol. Reprod. And Development**, 39: 147-152, 1994, Applicants' IDS).

Otaegui teach the synchronization of mouse embryos with nocodazole for production of embryonic cells in G1. See Abstract. In particular, they teach a method to synchronize 4-cell embryos in mitosis, and then used these cells I methods of nuclear transfer. See p. 147, 2nd col., 2nd ¶. They teach the detection of G1 cells utilizing UV microscopy and staining with Hoescht 33342, and then determined the detection of DNA synthesis by BrdU incorporation.

Accordingly, Otaegui anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The prior rejection of claims 1, 2, 5-13, 16-33, 56, 59-63 under 35 U.S.C. 103(a) as being unpatentable over Campbell *et al.* (cited previously) when taken with Boquest *et al.* (cited previously), in further view of Alberts *et al.* (cited previously) is withdrawn.

The claims 1, 3, 4 and 64-66 under 35 U.S.C. 103(a) as being unpatentable over Campbell *et al.* when taken with Boquest *et al.* and further in view of Prather *et al.*, Gadbois *et al* **PNAS**, 89: 8626-8630 and Collas *et al.* is withdrawn.

The prior rejections are withdrawn in view of Applicants' arguments, which state that the combination of references do not render the claimed invention obvious, because they do not provide a predictable and reliable method to isolate G1 cells for NT, and further, because it was both surprising and unexpected that using G1 cells would result in live born cloned animals.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Peter Paras, SPE of Art Unit 1632, at (571) 272-4517. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Thaian N. Ton/
Primary Examiner
Art Unit 1632